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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/606,909 | 06/29/2000 | Ronald J. Pettis | P-4901 | 7814 |

7590 11/24/2003

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| EXAMINER |
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HAYES, MICHAEL J

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| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 11/24/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,909

Applicant(s)

PETTIS ET AL.

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7, 10-24 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 10-16 and 28 is/are rejected.
- 7) ☒ Claim(s) 10-13 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/03 has been entered.

Information Disclosure Statement

The references cited in the IDS filed on 11/12/02, Paper No. 8 are not found in the case. The examiner would appreciate Applicant's resubmission of these references so they may be considered.

Election/Restrictions

Claims 29-30, submitted with amendment of Paper #6, received 10/28/2002, and claim 31 newly submitted, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 29-31 are directed to a method having higher plasma levels than subcutaneous injection, faster onset of detectable plasma levels than subcutaneous injection, or higher bioavailability than subcutaneous injection. The originally presented claims were directed to a method of delivering substance to an intradermal compartment at controlled volume and rate so that the substance is distributed in the plasma.

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Applicant made an election of these claims and received an office action on these originally presented claims. (See Paper No. 3, mailed 4/26/2002).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

Claims 10-13 and 15 are objected to because of the following informalities: Applicant has recited "mm" where it appears "µm" is required. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-7, 10-16, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The delivery of a substance at a controlled volume and rate as recited in claim 28 is not enabled in the specification. There is no enabling disclosure that would apprise one of ordinary skill in the art

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on how to control volume and rate as claimed by Applicant. There is no description of varying any control element and how that variation affects the delivered volume and rate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28, 2-7, 10-11, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by ALLEN et al. (U. S. Patent No. 6,334,856). ALLEN discloses a method of delivering insulin, growth hormones, and other drugs to an intradermal compartment using a needle or plurality of needles (4:9-30, 5:49-64) that has a length of a range 1µm - 1mm to attain a delivery depth of 0-100µm so that the delivery depth does not penetrate past the epidermis (col. 8, line 66 - col. 9, line 15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 12, 13, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over ALLEN as applied to claim 28 above and further in view of WAITZ et al. (U. S. Patent No. 5,484,417). Allen discloses the claimed invention except for the outlet at a depth of 250 μ m - 2mm and an exposed height of 0-1mm. Allen establishes a method of delivering a substance to the intradermal compartment, and discloses a delivery depth range of up to about 100 μ m to achieve this delivery. Allen also discloses that the length of the needle can be modified depending on attaining delivery at the desired depth within the epidermis (9:25-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the insertion depth to 250 μ m-1.5mm as long as the modified depth kept the delivery to the epidermis in order to account for biological variability. One of ordinary skill in the art would know from the teachings of Allen to increase the outlet depth in order to account for thicker stratum corneum and epidermis. Waitz teaches the use of bevel angles of 23-27° and such a bevel angle gives an exposed height in the range 0-300 μ m. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Waitz in the method of Allen in order to achieve the best microneedle performance as recognized and taught by Waitz (2:62-67).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh
17 November 2003



MICHAEL J. HAYES
PRIMARY EXAMINER